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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	1372.34	2429
21901	7590	02/08/2008	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			02/08/2008	PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/939,518
Filing Date: August 24, 2001
Appellant(s): JAROSZESKI ET AL.

Anton J. Hope
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/15/2007 appealing from the Office action mailed 6/14/2007.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

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(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,678,558

DIMMER et al.

1-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,678,558 B1 (Dimmer et al.).

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Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field including a plurality of substantially continuous electric fields in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell; wherein the duration of the applying step is in the range of 200ms to 100 seconds; wherein the electric field comprises a square, bipolar, or sinusoidal pulse waveform and wherein the electric field comprises a pulse comprising a combination of at least two of the indicated pulse waveforms wherein the injection step is by syringe injection; wherein the target tissue is skin or tumor tissue.

Specifically, Dimmer et al. teaches a method for delivering an agent such as a nucleic acid into a cell of a target tissue (such as skin or tumor tissue) using an electric signal that has a bipolar waveform (e.g., see abstract), wherein the agent is injected directly by needle and syringe (e.g., see column 2 lines 24-27), wherein the electric signal can have a bipolar, square or sinusoidal waveform (e.g., see column 5, lines 35-36; column 8, lines 17-30), wherein the electric signal can be a plurality of electric signals (e.g., see column 9, lines 10-16) wherein the electric field(s) are in the range of 1mV/cm to 200V/cm (e.g., 25V/cm or 100V/cm see column 10, lines 29-42); wherein the electric field is applied for a duration of 200ms-20minutes (e.g., most preferably about 50 μ s-400ms see column 10, lines 54-60). (Also see column 13, lines 7-7-

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19; column 14, lines 21-23; column 23, lines 1-11; column 24, lines 43-50; column 29, lines 12-15; claims 1, 10, 11, 16, 17, 25).

Dimmer also teaches applying an agent movement signal having a potential of about 5V-200V and more preferably about 10V-100V, having a duration of preferably about 100 μ s-10 seconds. Therefore, Dimmer teaches administration of an electric signal that meets the voltage and duration limitations of the claims. As such, the administration of the "agent movement signal" as described by Dimmer, would necessarily have the same result as the claimed method. In other words, since the agent movement signal taught by Dimmer meets the voltage and duration limitations of the claims it must have the same effect on the cells. Thus, application of the agent movement signal, as described by Dimmer would necessarily result in a change in the porosity of the cell sufficient to facilitate entry of the desired molecule into the cell.

Applicant is reminded that MPEP 2112.01 teaches, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Therefore, Dimmer et al. anticipates the instant claims.

(10) Response to Argument

1. Appellants argue that Dimmer does not teach each and every element of the claims.

Appellants contend that nowhere in Dimmer is it taught that the continuous electric field has a duration in excess of 50 μ s, while the claims require a continuous electric field of about 200ms to

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20 minutes. Appellants point out that Dimmer teaches that an electroporation treatment can include as many as 1,000,000 pulses within a 10 second duration. Appellants argue that Dimmer teaches the total electroporation signal duration signal is less than 10 seconds and can include up to 1,000,000 pulses, which is not the same as saying that a pulse duration is less than 10 seconds or more than 200ms. Appellants point out that Dimmer teaches “[t]herapeutic electric signals according to the present invention preferably have a pulse duration of less than about 50 μ s...” Appellants assert that nothing about the excerpted statements allows a conclusion that a pulse duration in excess of 50 μ s is taught by Dimmer, only that the sum of the pulse durations in Dimmer exceeds 50 μ s.

2. In response, it is respectfully pointed out that Dimmer explicitly claims an electroporation method wherein the electroporation method can comprise 1 to 1,000,000 pulses (e.g. see claim 5). Claim 5 does not explicitly indicate the duration of each pulse, and it would be improper to read any particular duration limitation into this claim. However, looking to the specification for guidance on the duration of the single pulse of claim 5, it is clear that the “total electroporation duration signal” can be “preferably less than about 10 seconds” and “most preferably about 50 μ s-400ms”. Therefore, if the total number of pulses is 1 (as is taught by at least claim 5 of Dimmer) then the “total electroporation duration signal” or “duration” of that single pulse certainly can be “less than about 10 seconds” and “most preferably about 50 μ s-400ms.” Therefore, Dimmer does teach a single pulse that is within the duration limitations of the instant claims. It is respectfully pointed out that Appellants appear to be focusing on the “preferable” and “most preferable” embodiments taught by Dimmer. However, Dimmer teaches more than the “preferable” and “most preferable” embodiments Appellants focus on.

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Considering the complete teaching of Dimmer, it is clear that Dimmer teaches an electroporation method that can be 1 to 1,000,000 pulses wherein the total duration of the electroporation signal is less than 10 seconds. As such, Dimmer teaches an electroporation method comprising 1 pulse having a duration of less than about 10 seconds and most preferably about 50 μ s-400ms.

Therefore, Dimmer anticipates the instant claims.

3. Appellants argue that the administration of the agent movement signal does not anticipate the claimed method. Appellants contend that Dimmer's agent movement signal does not meet the claim limitation of "effecting a change in porosity of the cell in the target tissue in response to the application of the electric field, the change in porosity sufficient to facilitate entry of the desired molecule into an interior of the cell." Appellant asserts that Dimmer recites ranges of agent movement signal voltages and pulse durations such that numerous voltages and durations would be possible and Dimmer does not teach a particular combination of voltage and duration within the agent movement signal as being sufficient to effect a change in porosity of the cell.

4. In response, it is noted that Appellants do not take issue with finding that agent movement signal taught by Dimmer meets the voltage and duration limitation of the claims. Rather, Appellants argument is that Dimmer does not teach that the agent movement signal effects a change in the porosity of the cell, as is required by the claims. However, if two methods comprise the same methods steps, these two methods would have the same result. Here, Dimmer teaches the application of an agent movement signal to a cell wherein the signal meets the limitations of claims. Therefore, the application of the agent movement signal would necessarily have the same result as applying the claimed electric field, which is a change in

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porosity of the cell. It is also respectfully pointed out that Dimmer explicitly teaches that the therapeutic electric signals can include an agent movement signal by itself, a bipolar signal by itself and or a combination of both (see column 14, lines 21-23). Therefore, the therapeutic electric signal can be an agent movement signal by itself, and application of the agent movement signal (which meets the voltage and duration limitations of the claims) by itself would necessarily have all of the same effects as applying the electric field of the claims, including effecting a change in porosity of the cell to which it is applied.

5. Appellants take issue with the position that the "continuous electric field" is not limited to a single electric pulse in the range and duration indicated. Appellants indicate that a "continuous electric field" or would correspond to what Dimmer calls a "therapeutic electric signal" (see page 17, lines 1-2). In essence, Appellants contend that the "continuous electric field" of the claims is a single electric pulse. Appellants assert that the Office is saying that multiple pulses which together have a total duration of "x" seconds can anticipate a single pulse having a duration of "x" seconds.

6. Let it be clear that the Office is NOT saying that multiple pulses which together have a total duration of "x" seconds can anticipate a single pulse having a duration of "x" seconds. The Office's position is that (1) Dimmer teaches a method of applying a single pulse that meets the voltage and range limitation of the instant claim, and (2) upon close examination of the instant claims, the "continuous electric field" of the claims is NOT limited to a single pulse; rather, the "continuous electric field" can comprise multiple electric pulses and it is only the "continuous

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electric field" that must have a duration of 200ms to 20 minutes. As indicated in the 6/14/2007 Final Office Action, claim 21 is drawn to a method of "applying a continuous electric field" to a cell and claim 24, which depends on claim 21, indicates that the "applying step comprises applying a plurality of substantially continuous electric pulses". Therefore, given the broadest reasonable interpretation of the claims consistent with the disclosure, the "continuous electric field" of the claims is not limited to a single pulse, but actually encompasses "a plurality" of pulses. Upon careful reading of claims, it is clear that it is the "continuous electric field", not a single pulse, which must have a duration of 200ms to 20 minutes. Since the claimed "continuous electric field" can comprise a plurality of pulses, the claims are not limited to a single pulse that has a duration of 200ms to 20 minutes. Rather, it would be the total duration of all pulses within the "continuous electric field" that would have to be 200ms to 20 minutes. Therefore, it is the Office's position that the claims are not necessarily limited to a method having a single electric pulse that has a duration of 200ms to 20 minutes; rather, the claims encompass applying a continuous electric field which can comprise a plurality of substantially continuous electric pulses wherein the duration of the continuous electric field is 200ms to 20 minutes. Dimmer certainly teaches this interpretation of the claims, as Appellants appear to acknowledge throughout their arguments.

In summary, Appellants argue that Dimmer does not teach the claimed method because (1) the claims require application of a continuous electric field for 200ms to 20 minutes and Dimmer does not teach applying a continuous electric field for a duration in excess of 50 μ s, (2) Dimmer's agent movement signal does not meet the claim limitation of "effecting a change in

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porosity of the cell in the target tissue in response to the application of the electric field, the change in porosity sufficient to facilitate entry of the desired molecule into an interior of the cell”, and (3) the Office has improperly rejected a single pulse of 200ms to 20 minutes using art that teaches applying multiple electric pulses wherein the duration of the total number of electric pulses add up to be within the range of 200ms to 20 minutes.

Appellants arguments are not persuasive because (1) Dimmer teaches an electroporation method having 1 to 1,000,000 pulses wherein the total duration of the pulse/pulses is less than about 10 seconds, most preferably about 50 μ s-400ms, (2) Dimmer teaches the application of an agent movement signal to a cell wherein the signal meets the limitations of claims; therefore, the application of the agent movement signal would necessarily have the same result as applying the claimed electric field (i.e., the agent movement signal would result in a change in porosity of the cell), and (3) the claimed “continuous electric field”, which must have a duration of 20ms to 20 minutes, actually encompasses “a plurality of substantially continuous electric pulses” (as indicated in claim 24); therefore, the “therapeutic electric signal” which comprises 1 to 1,000,000 electric pulses and has a duration of less than about 10 seconds, most preferably about 50 μ s-400ms, as taught by Dimmer, anticipates the claimed invention.

It is noted that the claims are not limited to applying a single electric pulse that has a duration of 200ms to 20 minutes. Rather, the claims encompass applying a continuous electric field which can comprise multiple pulses wherein the duration of the continuous electric field has a duration of 200ms to 20 minutes. Furthermore, even if the claims were limited to applying a single electric pulse for 200ms to 20 minutes, Dimmer teaches applying a single electric pulse for a duration within the required.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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1/30/2008

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